PATENT
1614-0251P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	R. VALENTA et al.	Conf.:	5581
Serial No.:	09/897,042	Group:	1644
Filed:	July 7, 2001	Examiner:	M. Jamroz
Re:	NON-ANAPHYLACTIC FORMS OF ALLERGENS AND THEIR USE		

Declaration under 37 C.F.R.§1.132

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Rudolf VALENTA, the undersigned, declares the following:

I am one of the co-inventors of the above-captioned application. As such, I am fully knowledgeable of the specification and the subject matter contained therein, including the invention encompassed by the claims.

In addition, to being one of the co-inventors of the present invention, I am also one of the co-authors of the journal article, C. Ebner et al. *J. Immunol.* 150: 1047-1054 (1993), which was cited by the Examiner in the Office Action of January 15, 2002. As one of the co-authors of the Ebner et al. reference, I am fully knowledgeable of the subject matter disclosed in the reference.

The present invention is drawn to immunogens derived from protein allergens. The immunogens of the present invention have the properties of being non-anaphylactic and of having an IgG epitope.

We have used the very same set of overlapping peptides as those described in the article by Ebner et al., *J. Immunol.* 150:1047-1054, 1993 (75 dodecapeptides with an overlap of 10 amino acids comprising the complete recombinant Bet v 1 sequence) to study the binding of human IgG antibodies to the peptides. Sera from birch pollen allergic patients containing IgG anti-Bet v 1 antibodies were tested for IgG reactivity to Bet v 1-derived peptides. The peptides were (i) dotted to nitrocellulose membranes and (ii) coated on ELISA plates. Complete recombinant Bet v 1 was used as a control in both cases. The membranes and the ELISA plates were then incubated with sera containing Bet v 1-specific IgG antibodies, and the presence of bound antibodies was detected with an alkaline-phosphatase-conjugated rabbit anti-human IgG antiserum. No antibodies binding to the peptides could be detected, neither on the membranes nor in the plates, whereas binding to the complete Bet v 1 sequence was detected. This demonstrates that the peptides disclosed by Ebner et al. do not contain epitopes for human IgG antibodies.

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As such, in my opinion, the immunogens of the present invention which have an IgG epitope would not be anticipated by, nor obvious over, the peptides of Ebner et al.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Rudolf VALENTA

MARCH 11, 2002
Date

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